

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**(Case No. 02-1049-B)**

In application of	)	
	)	
Jenny, <i>et al.</i>	)	Examiner: Susan Marie Hanley
	)	
Serial No. 10/534,187	)	
Patent No. 7,604,932	)	
	)	Group Art Unit: 1651
371 Completion Date: January 9, 2005	)	
Entered National Stage: May 13, 2005	)	
	)	
For: Assay For Tissue Factor in a Sample	)	Confirmation No.: 5272

Mail Stop Patent Ext.  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT**  
**DETERMINATION UNDER 37 C.F.R. 1.705(d)**

Sir:

Pursuant to 37 C.F.R. 1.705(d), Applicants request reconsideration of the patent term adjustment indicated in the Issue Notification mailed September 30, 2009 for U.S. Patent No. 7,604,932 (the '932 patent). Applicants respectfully contend that as of the issuance of the patent on October 20, 2009, the correct patent term adjustment should be 685 days, and not 213 days as indicated on the Issue Notification.

Applicants' provide a statement of the facts involved, including the bases under 37 C.F.R. 1.702 for Applicants' calculation of the correct patent term adjustment of 685 days, beginning on page 2 of this paper.

**Remarks:**

Responsive to the Determination of Patent Term Adjustment posted on the Patent Application Information Retrieval System (PAIR) and provided with the Issue Notification mailed September 30, 2009, and in light of the recent ruling in *Wyeth v. Dudas*, 88 U.S.P.Q.2d 1538 (D.D.C. 2008), Applicants submit this Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. 1.705(d) along with the required fee set forth in 1.18(e), and respectfully request that the '932 patent be granted an additional 472 days of patent term. As stated in 37 C.F.R. 1.705(d):

If there is a revision to the patent term adjustment indicated in the notice of allowance, the patent will indicate the revised patent term adjustment. If the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section. Any request for reconsideration under this section that raises issues that were raised, or could have been raised, in an application for patent term adjustment under paragraph (b) of this section shall be dismissed as untimely as to those issues.

This request is being submitted within two months of the issuance of the patent (October 20, 2009), thus it complies with the relevant deadline specified in 37 C.F.R. 1.705. As the additional patent term was unable to be calculated until the patent issue date was known, Applicants could not have raised this request for reconsideration under 37 C.F.R. 1.705(b). Thus, Applicants contend this request is timely.

The data available on PAIR indicates that the instant application has been granted 213 days of Patent Term Adjustment. Applicants submit that, due to the recent *Wyeth* decision, the correct Patent Term Adjustment should be 685 days. Applicants, therefore, request that the above-captioned allowed application be granted an additional 472 days of patent term.

Pursuant to 37 C.F.R. 1.705(b)(2)(iii), Applicants note that the '932 patent is not subject to a terminal disclaimer.

**Calculation:**

Applicants agree with the Patent Office's initial determination, which, for purposes of this request and in keeping with the explanation provided in *Wyeth*, Applicants will refer to as the "A-delay." In the "A-delay" the Patent Office delayed prosecution by issuing the first communication (Restriction Requirement, January 4, 2008) 14 months plus 360 days after the fulfillment of the requirements of 35 U.S.C. 371 (37 CFR 1.703(a)(1)) and by mailing the notice of allowance 4 months plus 50 days after Applicants' response to the non-final office action (37 CFR 1.703(a)(2)), resulting in a USPTO "A-delay" of 410 total days as illustrated in Table 1 below.

**Table 1: PTO A-Delay**

<b>USPTO Delay under 37 C.F.R. 1.703</b>	<b>Date of Applicant Action</b>	<b>Expected Date of USPTO Action</b>	<b>Actual Date of USPTO Action</b>	<b>USPTO Delay</b>	<b>Correctly calculated in the original PTA calculation on PAIR?</b>
1.703(a)(1)	Nov. 9, 2005 (371 completion date)	Jan. 9, 2007	Jan. 4, 2008 (restriction requirement mailed)	360 days	YES
1.703(a)(2)	Dec. 22, 2008 (response after non-final office action)	Apr. 22, 2009	Jun. 11, 2009 (notice of allowance mailed)	50 days	YES
<b>Total PTO Delay</b>				<b>410 days</b>	<b>YES</b>

Applicants delayed prosecution by filing a response a restriction requirement 3 months plus 31 days after the mailing of the restriction requirement and by filing a response to a non-final office action 3 months plus 61 days after the mailing of the non-final office action. Applicants also delayed prosecution 105 days by filing a supplemental paper after a reply had been filed (37 CFR 1.704(c)(8)). Therefore, Applicants were responsible for a total of 92 days of delay under 37 CFR 1.704(b) as illustrated in Table 2 below and 105 days of delay under 37 CFR 1.704(c) as illustrated in

Table 3 below. Thus, total applicant delay is 197 days.

**Table 2: Applicant Delay under 37 C.F.R. 1.704(b)**

<b>Applicant Delay under 37 C.F.R. 1.704(b)</b>	<b>Date of USPTO Action</b>	<b>Expected Date of Applicant Action</b>	<b>Actual Date of Applicant Action</b>	<b>Applicant Delay</b>	<b>Correctly calculated in the original PTA calculation on PAIR?</b>
1.704(b)	Jan. 4, 2008 (restriction requirement mailed)	Apr. 4, 2008	May 5, 2008 (response to restriction requirement)	31 days	YES
1.704(b)	Jul. 22, 2008 (non-final rejection mailed)	Oct. 22, 2008	Dec. 22, 2008 (response to non-final rejection)	61 days	YES
<b>Total Applicant Delay under 37 C.F.R. 1.704(b)</b>				<b>92 days</b>	<b>YES</b>

**Table 3: Applicant Delay under 37 C.F.R. 1.704(c)**

<b>Applicant Delay under 37 C.F.R. 1.704(c)</b>	<b>Date of First Applicant Action</b>	<b>Date of Supplemental Applicant Action</b>	<b>Applicant Delay</b>	<b>Correctly calculated in the original PTA calculation on PAIR?</b>
1.704(c)(8)	Dec. 22, 2008 (response to non-final action)	Apr. 6, 2009 (supplemental paper filed (affidavit))	105 days	YES
<b>Total Applicant Delay under 37 C.F.R. 1.704(c)</b>			<b>105 days</b>	<b>YES</b>

The Patent Office, however, has **not** included in the Patent Term Adjustment the days related to the “B-delay,” which are the days delay resulting from an application pending longer than three years. According to 37 C.F.R. 1.703(b):

The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued...

The national phase for the ‘932 patent commenced on May 13, 2005. The ‘932 patent issued on October 20, 2009, which is three years plus 525 days after the national stage commencement (37 CFR 1.703(b)) as illustrated in Table 4 below.

**Table 4: PTO B-Delay**

USPTO Delay under 37 C.F.R. 1.703	Date of Applicant Action	Expected Date of USPTO Action	Actual Date of USPTO Action	USPTO Delay	Correctly calculated in the original PTA calculation on PAIR?
1.703(b)	May 13, 2005 (371 national stage)	May 13, 2008	Oct. 20, 2009 (patent to issue)	525 days	NO
<b>Total PTO Delay</b>				<b>525 days</b>	<b>NO</b>

The *Wyeth* decision states that “the ‘A period’ and ‘B period’ overlap only if they occur on the same calendar day or days.” *Wyeth*, 88 U.S.P.Q.2d at 1540. In this instance, the overlap of “A-delay” and “B-delay” is 50 days.

Thus, according to the *Wyeth* decision, Applicants are entitled to both the “A-delay” of 410 days and the “B-delay” of 525 days, minus any overlap that occurs on the same calendar days (50 days), and minus any Applicant delay (197 days). Thus, the total Patent Term Adjustment due to both the “A” and “B” delays, minus any overlap and minus Applicant delay is 685 days as illustrated in Table 5 below.

**Table 5: Calculation of Patent Term Adjustment**

PTO A-Delay	410 days
PTO B-Delay	525 days
Applicant Delay under 37 C.F.R. 1.704(b)	92 days
Applicant Delay under 37 C.F.R. 1.704(c)	105 days
Overlap	50 days
<b>Patent Term Adjustment:</b>	<b>685 days</b>

For these reasons, the Patent Term Adjustment for this case should be 685 days. In light of the foregoing, the Applicants respectfully request that an additional 472 days of Patent Term Adjustment be added to the patent term for Patent Office delay, resulting in a total Patent Term Adjustment of 685 days.

If Examiner Hanley believes it to be helpful, the Examiner is invited to contact the undersigned representative at 312-913-2114. The Commissioner is authorized to charge the amount of \$200 for the filing of an application for patent term adjustment under 37 C.F.R. 1.705(b), pursuant to 37 C.F.R. 1.18(e), to Deposit Account No. 13-2490.

Respectfully submitted,  
**McDonnell Boehnen Hulbert & Berghoff LLP**

Date: October 21, 2009

/Bradley W. Crawford/

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